Clinical Trials Management Systems Workspace
Face-to-Face Meeting
Oregon Health & Science University
SESSION: SIG Breakout Report Outs

Session Information	**Date: May 30, 2007** **Time: 4:30 p.m.–5:00 p.m. PDT** **Presenter/Lead: CTMS/DSIC Breakout Session Leads (George Komatsoulis/Wendy Patterson, Christo Andonyadis/Rachel Nosowsky, John Speakman/Elaine Brock)** **Facilitator: Julie Holtzople** **Scribe: Daniela Smith**
Executive Summary	The Breakout Session Leads from the Clinical Trials Management System (CTMS) and Data Sharing & Intellectual Capital (DSIC) Workspaces representing those Special Interest Groups (SIG) that were discussed during the afternoon sessions of Meeting Day One, reported on the summary outcomes from their respective sessions. In each group, participants expressed their ideas and concerns regarding what kinds of data can be stored and shared, and how the data should be accessed. Each group developed different requirements and raised issues that should be addressed going forward.
Discussion	Study Conduct SIG—George Komatsoulis & Wendy Patterson • Among the Study Conduct projects and /activities discussed, a high level of sensitivity was expressed, particularly concerning Protected Health Information (PHI). • Many Intellectual Property (IP) issues (i.e., study design, set up, parameters) arise depending on who the trial sponsor is (if NCI sponsors, not IP protective; if non-NCI private sponsors, lead to more IP issues) and how the information is being used. • It became apparent that in looking at the entire bolus of information collected in an application, that there is sensitive information that will need to remain at the local institution. If de-identified information can be extracted into a data subset, it will be important to collect that information using the tools that CTMS is developing, and to have derivative datasets that can be pushed out to a broader set of users. The original data set should remain available. Reporting/Sharing SIG—Christo Andonyadis & Rachel Nosowsky • Several of the Reporting/Sharing applications discussed in the breakout house the same data. Participants in this session rewrote the names of the projects as categories of data types. • There was substantial discussion concerning protocol versus patient and individual versus aggregate data. • Because there are many similarities in patient data, in general, the more aggregated the data is, the more de-identified and less sensitive it becomes. • There are certain levels of data that must be extracted. Certain data subsets may be extracted, while others may have higher sensitivity and require more rules and role-based access issues to address their use. Planning/Monitoring SIG—John Speakman • Institutions may regard investigator-initiated protocols as containing IP value. Participants noted concern regarding the issue of limited or restricted patient access to protocols.

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Scoped consent forms are needed for people to sign to anticipate future forms of data sharing.
An issue was raised regarding potential investigator “spamming” to solicit participants in trials. Some form of “opt-out” registry may be necessary.

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<tr><th>Assigned To</th><th>Description</th><th>Due Date</th></tr>
<tr><td>CTMS /DSIC Workspaces</td><td>The requirements and issues gathered from each of these SIG breakout sessions will be reviewed and considered in the course of SIG activities going forward.</td><td>Ongoing</td></tr>
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<tr><td>Attendance</td><td>All Meeting Day One attendees were present for the Breakout Session Report Outs.</td></tr>
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